Remarks

The Applicants have amended Claims 2 and 16 into independent form. Entry into the official file is respectfully requested inasmuch as the amendments are merely a formality placing dependent claims into independent form, there is no change in scope of coverage sought, no requirement for further search and no new issues are raised by these amendments.

Claims 1 – 9 and 16 stand provisionally rejected on the grounds of non-statutory obviousness-type double patenting over Claims 38 – 42 of co-pending Application No. 10/143,111; Claims 1 – 21 of co-pending Application No. 11/447,560; and Claims 1 – 9 of co-pending Application No. 11/447,714. The Applicants respectfully request that further treatment of this rejection be held in abeyance inasmuch as the rejection is provisional.

Claims 1 and 3 – 8 stand rejected under 35 USC §112 as failing to comply with the written description requirement. The Applicants note with appreciation the Examiner's detailed comments, including the continued reliance on Eli Lilly. The Applicants respectfully submit, however, that all of Claims 1 and 3 – 8 are in full compliance with 35 USC §112. Details are set forth below.

The fundamental basis of the rejection may be found in the following statement:

> In particular, the specification as original [sic] filed fails to provide sufficient written bases of any of the agents demonstrating wherein possession of use of the broad terms: **an active pharmaceutical ingredient**. The mere fact that Applicant may have discovered one type of active pharmaceutical ingredient formed in the instant process is not sufficient to claim the entire genus.

The Applicants respectfully submit that they did not discover "one type of active pharmaceutical ingredient." The Applicants did not discover a product. Instead, the Applicants discovered a process for preparing a controlled release oral dosage form. Thus, the novelty and non-obviousness of the subject matter from Claims 1 and 3 – 8 is directed to a process, not a product

and the process is for preparing a controlled release oral dosage form, not a process for preparing an active pharmaceutical ingredient.

Claims 1 and 3 – 8 employ an active pharmaceutical ingredient in their process of preparing a controlled release oral dosage form. However, that is not the crux of the subject matter of Claims 1 and 3 – 8. As a consequence, the Applicants surely envisioned that their process for preparing a controlled release oral dosage form would be applicable to active pharmaceutical ingredients. There was surely no reason for the Applicants to restrict the process or restrict the pharmaceutical component added to their resulting controlled release oral dosage form. It simply would not be logical to unnecessarily restrict the applicability of the process and the resulting controlled release oral dosage form.

This broad and intuitive understanding as would readily be gleaned by one skilled in the art is reflected throughout the Applicants' disclosure. Specifically, the Applicants disclose on Page 3, beginning at Line 9, that the method can be used "with a wide range of active pharmaceutical compounds." That disclosure readily confirms the Applicants' point above that the Applicants discovered a process for preparing a controlled release oral dosage form and that it simply would not make sense to unnecessarily restrict the applicability of that process and the resulting controlled release oral dosage form to a narrow species. Thus, the Applicants' specific statement that the method can be used "with a wide range of active pharmaceutical compounds" means that the Applicants surely had within their possession at the time the Application was filed that the active pharmaceutical compounds that could be used in conjunction with the claimed process for preparing a controlled release oral dosage form are extremely broad. The use of "a wide range" is very expansive and non-limiting.

Lines 14 and 15 of Page 4 are even more expansive. In particular, that text recites that

"the active ingredient may be any therapeutically active pharmaceutical ingredient(s) or a combination of active ingredients." This statement is quite definitive. In particular, the use of the word "any" is indicative of the fact that the Applicants were clearly in possession of the subject matter of Claims 1 and 3 – 8 at the time the Application was filed. "Any" is a critical word and may be defined in any number of representative ways such as the following representative examples: "every," "all," "exceeding normal limits, as in size or duration" and "whatever kind, quantity, or number." What the deliberate use of this term means in the context of this disclosure and the subject matter of Claims 1 and 3 – 8 is that the Applicants fully intended at the time this Application was filed that their process for producing a controlled release oral dosage form could and would apply to an extremely wide range of active pharmaceutical ingredients, which is in of itself of a well known term. There was no intention to be restricted to a single species or a single compound.

The Applicants respectfully submit that the above disclosure fully satisfies §112, first paragraph. However, the Applicants went further and provided a list of more than a dozen "preferred" active ingredients. Use of the term "preferred" inherently implies that the list of active ingredients is much larger than those specifically named. Nonetheless, the Applicants identified twelve (12) specific types of active pharmaceutical ingredients. Then, the Applicants went even further and not only recited the dozens specific active ingredients, but also expanded that list to include salt or mixtures thereof. The number of salts for the dozens specifically listed preferred active ingredients would raise the total types of species listed to dozen and dozens. Then, if mixtures are considered, there are dozens and dozens of more possibilities. Thus, the Applicants "preferred" active ingredients include many dozens if not hundreds of possible active pharmaceutical ingredients as recited in Claim 1.

The Applicants respectfully submit that the facts in this case render Eli Lilly inapplicable. There is no evidence in Eli Lilly that the terminology at issue in that case was described or disclosed or defined by the Applicants in that Application. As noted above, the Applicants used broad language to communicate their intention that the possible range of active pharmaceutical ingredients would be quite large. They used the specific terms "wide range" and "any." Moreover, the Applicants refer to "preferred" active ingredients and then provided a list of dozens of specific types of active ingredients, mixtures of those specific types of active ingredients and salts thereof that encompass dozens if not many hundreds of possible active ingredients. There is nothing in Eli Lilly that indicates those types of facts. Instead, the facts were quite different in Eli Lilly. Thus, Eli Lilly is inapposite.

However, there are decisions that are more applicable as described below.

In LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005), the Federal Circuit reasoned that the written description requirement of 35 USC §112 is rigorous, but not exhaustive, noting that is "is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention." The CCPA also set forth a long standing precedent rejecting a rigid interpretation of the written description requirement, holding that even a single species may be sufficient to describe a broad genus. This is discussed In re Herschler, 591 F.2d 693 (CCPA 1979) holding that a single species described in the Specification was sufficient to describe a claim drawn to a broad genus.

In Herschler, the court found adequate written description support for broad claims to processes for topically administering a physiologically active steroidal agent to a human or animal by concurrently administering the steroidal agent and dimethyl sulfoxide ("DMSO"),

even though the specification disclosed only one example of a "physiologically active steroidal agent." With respect to a written description of a broad class of compounds, Herschler noted that the disclosure must provide a measure of predictability for the utility described for that class. However, the court reasoned that claimed subject matter need not be described *in haec verba* to satisfy the description requirement, nor was it necessary that the application describe the claim limitations exactly. Herschler *citing* In re Smith, 59 CCPA 1025, 458 F.2d 1389, 173 USPQ 679 (1972); In re Smythe, 480 F.2d 1376, 178 USPQ 279 (CCPA 1973). Even though the class of steroidal agent was large and varied, the court held that one having ordinary skill in this art would have found the use of the genus of steroids to be apparent in the written description.

The court there emphasized that, because the application was drawn to a combination of the DMSO solvent and the steroidal agents and not to the actual "novel 'steroidal agents,'" less description of the agents was necessary. That point is critical in this case. Indeed, Herschler held that claims drawn to the use of known chemical compounds in a manner auxiliary to the invention must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds. Thus, as applied to the example of a claim drawn to a drug delivery device, the class of compounds that may be delivered need not be described in the same manner as if the claim were directed to the actual compounds.

Here, like Herschler, the claims are drawn to a process using known chemical compounds in a manner auxiliary to the claimed process. Therefore, according to Herschler, 35 USC §112 requires a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds. The Applicants' reference to use of the claimed dosage from with "a wide range of active pharmaceutical compounds" on page 3 at line 9 leads one of skill in the art to that class of compounds. Furthermore, because the result of using the claimed

dosage form with any of the broad genus of "active pharmaceutical ingredients" is predictable, only a limited number of species are required to adequately describe the whole genus. Whether the physiological activity of active compounds differs is irrelevant because the result of preparing the dosage form is identical and predictable: the active pharmaceutical ingredient is formulated into a controlled dosage form. Accordingly, one of skill in the art would appreciate that the genus of active pharmaceutical ingredients was contemplated and described in the Specification.

The Applicants, therefore, respectfully submit that Claims 1 and 3 – 8 are in full compliance with §112 inasmuch as the Applicants have factually demonstrated that they envisioned a very broad range of active pharmaceutical ingredients that could be used in their claimed process for preparing a controlled release oral dosage form. Withdrawal of the rejection is respectfully requested.

In light of the foregoing, the Applicants respectfully submit that the entire Application is now in condition for allowance, which is respectfully requested.

Respectfully submitted,

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